Gen-ECT-ic data collection form v10 from 05/June/2019

Sections 1-7 are part of the minimum and sections 8-16 for the extended data set. The instructions and data relate to a current or any previous acute course, i.e. non-maintenance series, index episode, or any completed ECT series for acute course. Data collection could be either retrospective or prospective.

1. **To qualify for the study**, questions in sections 1-4 need to be answered for inclusion.
2. **Retrospective data collection I** of patients who had ECT and/or treatment resistant depression in the past; sources for minimal data may be biobanks, registries, or can be easily collected from existing case notes or by recall of the treating doctor; Minimal data include at least diagnosis, age, gender, past ECT treatment, treatment resistant depression (items 1-4);
3. **Retrospective data collection II** of patients who had ECT in the past, where case notes are accessible and data had been collected already; using this approach the minimal data (1-7) and possibly some of the extended data can be collected (8-16);
4. **Prospective data collection** of patients coming in for a course of ECT: data can be collected for baseline and at the end of the last ECT of the current course of ECT and minimal and extended data can be collected.

1. Basic Information (minimum)

1.1. Study ID format: GenECT-IC-SITE ID-PARTICIPANT ID (example: GenECT-IC-ADL-1234567)

GenECT-IC-_____

1.2. What is the ID of the blood sample?_____ □ Same as Study ID

1.3. Name of centre the subject was recruited at? _____

2. Demographics (minimum)

2.1. The following information has all been validated based on available medical records Y / N

2.2. The information was gathered by research interview Y / N or from a registry Y / N

2.3. Date of Birth _____/_____/_____ Day /Month / Year OR Age at assessment (whole numbers) _____

2.4. Biological sex (assigned sex at birth) □ Male □ Female

2.5. Enter the years of education completed (including primary, secondary, tertiary school, apprenticeship). Completion of high school=12years of education, completion of college=16years of education.
Total number of years of education completed:_____ □Unknown

2.6. What is the subject's ethnicity? (Ethnicity means belonging and attachment to a distinct group of a larger population that shares their ancestry, colour, language or religion)?
Select all that apply: □Caucasian □Latino/Hispanic □Middle Eastern □African □Caribbean □South Asian □East Asian □Aboriginal □Pacific Islander □Other

Please write in other ethnicities here: _____

3. Inclusion criteria (minimum)

3.1. Has the subject ever received ECT or is about to receive ECT for the first time?
Y / N

3.2. Does the patient have a diagnosis of treatment resistant (unipolar or bipolar) depression?
Y / N / Not obtainable
(Treatment resistant depression is defined as: Evidence of failure of at least two antidepressants at recommended minimal adequate dose in trials lasting >=6 weeks.)

3.3. Has the subject ever had a diagnosis of Major Depressive Disorder?
Y / N

3.4. Has the subject ever had a diagnosis of Bipolar Disorder?
Y / N

3.5. Does the subject meet the inclusion criteria based on information available at time of data entry? Y / N (subject must answer 'yes' to question 3.1 or 3.2 **and** 3.3 or 3.4)

4. Consent Form (minimum)

4.1. Consent requirements (Select most appropriate):
- □Consent for this study not required
- □Consent previously obtained / sample from previous study or biobank / registry
- □Sample/data available, but extra consent needed
- □Consent needed for recruitment into study and sample collection

If consent still needs to be obtained, please add:

4.2. Consent type (select): □by the person □by a proxy

4.3. Informed consent form signed at (site) _____

4.4. Date subject signed consent / / Day /Month / Year

4.5. Person that gave consent for study (Do not complete if this violates local regulations)
_____

4.6. The data provided here includes (Select all appropriate responses):

□ Basic Data (Sections 1-4 only)

□ Retrospective Data Collection only

□ Prospective Data Collection

4.7. Permission to recontact subject? □Y / □N

5. **Treatment evaluation of ECT series referred to in this survey (acute course, i.e. non-maintenance series, index episode, or any completed ECT series for acute course) (minimum) :** (for retrospective patients “index” refers to the past episode for which they were treated with ECT and for which clinical information is available). **Skip to section 8 if the answer to question 3.1 above is No.**

5.1. Diagnostic indication for ECT series as referred to in this survey? (select one)

Major depressive disorder
 Unipolar melancholic depressive episode (Anhedonia, lack of mood reactivity, and 3 of the following: (Depression, Severe weight loss/lack of appetite, Psychomotor retardation/agitation, early morning awakening, excessive guilt, worse mood in morning)
 Unipolar non-melancholic episode
 Unipolar psychotic depressive episode
 Unipolar depressive episode (unspecified)

Bipolar disorder
 Major depression
 Psychotic depression
 Mania
 Mania with psychotic features
 Mixed mood
 Mixed mood with psychotic features

Schizoaffective disorder
 Major depression
 Mania
 Mixed mood

Schizophrenia/Schizoaffective
 Positive psychotic symptoms

Catatonia
 Unipolar depression
 Bipolar disorder
 Schizophrenia
 Organic
 Neurodevelopmental

 Neuroleptic malignant syndrome

 Other (specify): _____

5.2. Main clinical reason for ECT? (select)
- □Failure of medication
- □High suicide risk
- □Severe aggression/agitation
- □Inadequate oral intake
- □ Previous good ECT response
- □ Patient preference
- □ Intolerable medication side effects

5.3. Predominant electrode placement? (select)

□unilateral □bitemporal □bifrontal □other

5.4. If other type of placement please specify here _____

5.5. Anaesthetic agents used (select all relevant)
- □Methohexitone
- □Thiopentone
- □Propofol
- □Etomidate
- □Ketamine
- □Succinylcholine
- □ Other (specify): _____

5.6. ECT administration

Pulse width (msec; select one): □0.25-0.3; □0.5-1.0; □>1.0
Method of stimulus dosing (select one): □fixed, □based on ST, □age-based,
□other (please specify)_____
Initial Stimulus dose (mC):_____ (For Thymatron this is 504x%/100)
Final dose (mC): _____
Switch to another type ECT? If yes, please specify: _____
Number of ECT sessions in this acute course: ___

5.7. Is the patient taking any psychotropic drugs during this current ECT series?
Yes / No

5.8. Clinical response to ECT assessed □ prospectively or □ retrospectively based on □clinical judgment/recall by treatment providers □ retrospective chart review based assignment

5.9. ECT was administered as an □ inpatient □ outpatient □community sample □ unknown

6. Baseline assessment before ECT series referred to in this survey (minimum)

6.1. Was baseline pre ECT mood and cognitive assessment completed? Y / N / Not obtainable
(If not obtainable skip to 6.6)

6.2. Baseline affective symptoms before ECT series was assessed by: (Select all as appropriate)

□HDRS **AND/OR** □ MADRS **AND/OR** □ BDI **AND/OR** □ CES-D **AND/OR** □YMRS **AND/OR** □ QIDS **AND/OR** □CGI-S **OR** □Unobtainable due to severity

Other (Write other scale here) _____

6.3. Baseline symptoms before ECT total score(s) =

6.4. Baseline cognition before ECT series was assessed by: (Select all as appropriate)

□MOCA **AND/OR** □THINC-it **AND/OR** □MMSE **AND/OR** □mMMSE **AND/OR** □ECA **OR** □Unobtainable due to severity

Other (Write other scale here)_____

6.5. Baseline cognition total score(s) before ECT =

6.6. Was a baseline assessment of autobiographical data completed?
Yes / No / Not obtainable (if no or not obtainable skip to 6.8)

6.7. Baseline assessment of autobiographical data was assessed by:
□Columbia AMI (CUAMI) **AND/OR** □CUAMI-SF **AND/OR** □Other scale (Write other scale here) _____

6.8. Assessment of autobiographical data total score(s) = _____

6.9. Was a baseline functional assessment completed? Y / N / Not obtainable
(if no or not obtainable skip to 6.11)

6.10. Baseline assessment of function was assessed by
□Global Assessment of Function (GAF) □AND/OR Functional assessment short-test(FAST)

6.11. Baseline functional assessment total score(s)= _____

(6.12 for paper data collection please attach copies of score sheets to end of questionnaire)
Prior to attaching/uploading mood/cognition scoring, please deidentify them (black out PHI)

6.12. Please upload baseline scanned;

6.12.1. mood scores (with item scores), 6.12.2 cognition scores 6.12.3 autobiographical scales, 6.12.4 function scales, if available, here

6.13. Did the patient have baseline MRI of the head? Yes / No / Unknown

6.14. Do you have/ plan to collect any other biosamples (apart from DNA?) Yes / No
Specify: □RNA □Metabolomic □ CSF □ Microbiome □ Other(s)_____

7. Post-ECT assessment (minimum): Please address this section at the conclusion of the ECT series referred to in this survey or when sufficient data is available.

7.1. Reason for cessation of ECT (select one)

- □Complete response
- □Partial response
- □No response
- □Cognitive side effects
- □ECT-related medical complications – please specify: _____
- □Withdrawal of consent
- □Other (specify):
- □ECT was continued due to □Partial response □Complete response

7.2. Was ECT terminated due to Manic Switch? (Mania Definition: 7 days with ≥3 of grandiosity, decreased sleep, pressured speech, racing thoughts, distractibility, increased activity, excessive involvement in pleasurable activities)
Yes / No

7.3. Was ECT terminated due to other complications? Yes / No
(Specify)_____

7.4. Was mood and cognition assessed after an ECT series (e.g. 6-12 sessions of ECT done 2-3 times weekly)? Yes / No / Unobtainable

7.4.1 How many ECT treatments for acute series were completed prior to assessment(s) (whether the series was completed or terminated)?
_____Number

7.5. Post-ECT affective symptoms was assessed by: (select all as appropriate)

□HDRS **AND/OR** □MADRS **AND/OR** □BDI **AND/OR** □CES-D **AND/OR** □YMRS **AND/OR** □QIDS **AND/OR** □CGI-S **AND/OR** □CGI-I

Other (Write other scale here) _____

7.6. Post- ECT symptoms total score =

7.7. Post-ECT cognition was assessed by: (select all as appropriate)

□MOCA **AND/OR** □ THINC-it **AND/OR** □ MMSE **AND/OR** □ mMMSE **AND/OR** □ ECCA □ Other (Write other scale here)_____

7.8. Post-ECT cognition total score =

7.9. Was a Post-ECT assessment of autobiographical data completed?
Yes / No / Not obtainable (if no or not obtainable skip to 7.12)

7.10. Post-ECT autobiographical memory was assessed by (select all appropriate)

□Columbia AMI (CUAMI) **AND/OR** □CUAMI-SF **AND/OR** □Other scale
(Write other scale here) _____

7.11. Post-ECT autobiographical memory (i) total raw score= (ii) % consistency score=

7.12. CGI-Improvement score for ECT series (select one)

□1. Very much improved
□2. Much improved
□3. Minimally improved
□4. No change
□5. Minimally worse
□6. Much worse
□7. Very much worse

Functional assessment: Only complete if Pre-ECT GAF or FAST score obtained

7.13. Post ECT GAF score =

7.14. Post-ECT FAST score =

7.15. Was continuation/maintenance ECT required? Y / N / Unobtainable

Prior to attaching/uploading original scoring, please deidentify them (black out PHI)
(7.16-7.18: for paper data collection please attach copies of score sheets to end of questionnaire)

7.16. Please upload post-ECT scanned mood scores (with item scores), if available, here

7.17. Please upload post-ECT scanned cognition scores (with item scores), if available, here

7.18. Please upload baseline and post-ECT scanned autobiographical data scores (with item scores), if available, here

Sections 8-16 are part of the extended data series. We hope to collect as much historical data as possible on our subjects, however recognize that the availability of such records may be limited, especially for retrospective collection, and samples available in biobanks with limited attached records. Please complete these as able.

8. Psychiatric History: (extended)

8.1. Current smoker? Y / N □Unknown

8.2. Number of psychiatric hospitalizations?_____(Unknown/unobtainable)

8.3. Number of suicide attempts?_____(Unknown/unobtainable)

8.4. Number of total antidepressants ever trialled to treat depression (select)
□ Not obtainable □0 □1 □2-3 □4-5 □>5

8.5. Select all lifetime psychiatric diagnoses:
□Schizophrenia; □Schizoaffective disorder; □Bipolar I; □Bipolar II; □Major depressive disorder; □Dysthymia; □Generalized anxiety disorder; □Social phobia; □Panic disorder; □Obsessive-compulsive disorder; □Post-traumatic stress disorder; Anorexia nervosa; □Bulimia nervosa; □Autism spectrum disorder, □Intellectual disability □alcohol abuse; □alcohol dependence; □ nicotine dependence; □drug induced psychosis; □drug induced mania; □other

Please write down “other” psychiatric diagnoses here

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9. Unipolar Depression: If the subject has had a diagnosis of major depressive disorder as indicated in 3.3, please fill in this section (extended)

9.1. Age when patient experienced first unequivocal major depressive episode (may have gone untreated)
_____ □Unknown

9.2. Number of depressive episodes _____ □Unknown

9.3. Is there a type of depression that is clearly predominant in this patient's presentation? (Select all appropriate)

□Melancholic □ Atypical □ Psychotic □Catatonia □No clear pattern □Unknown

9.4. Did past treatments for depression include? Response? (select all appropriate)

Psychotherapy	□Unknown	□No past trial	□Unknown Response	□Good	□Partial □Poor
Transcranial Magnetic Stimulation	□Unknown	□No past trial	□Unknown Response	□Good	□Partial □Poor
Transcranial Direct Current Stimulation	□Unknown	□No past trial	□Unknown Response	□Good	□Partial □Poor

Ketamine □Unknown □No past trial □Unknown Response □Good □Partial □Poor

9.5. Class of medications trialled ever (select drug class and response if appropriate)

SSRIs (fluoxetine, sertraline, paroxetine, (es)citalopram)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

SNRIs (venlafaxine, duloxetine)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

TCAs (amitriptyline, amoxapine, desipramine, imipramine, nortriptyline, protriptyline, trimipramine)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

MAOis (isocarboxazid, phenelzine, selegiline, tranylcypromine)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

Atypical antidepressant agents (bupropion, mirtazapine, nefazodone, trazodone, vilazodone, vortioxetine)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

Combination use of above antidepressants
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

Please mark types used in list below

Atypical antipsychotics	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Benzodiazepine	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Lithium	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Anticonvulsant	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
T3 (Liothyronine)	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Buspirone	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor

10. Bipolar spectrum Mania – Lifetime History (extended): If the subject has had a diagnosis of bipolar disorder as indicated in 3.4, Please fill in this section

10.1. Has the subject ever had manic or hypomanic symptoms? Yes / No
(If none, skip to Medical History-13)

10.2. Was the first mood episode ever a depressive episode or manic episode?
□Depression □Mania □Unknown

10.3. What type of manic episodes has the patient ever had (select one)?
Mania Definition: 7 days with ≥3 of grandiosity, decreased sleep, pressured speech, racing thoughts, distractibility, increased activity, excessive involvement in pleasurable activities

□ 1. ≥2 “clean” manic episodes (not due to street drug use or antidepressants)
□ 2. 1 “clean” manic episode
□ 3. 1 or more manic episode but all were due to street drugs or antidepressants
□ 4. History of hypomania but no mania

10.4. Age of first diagnosed manic episode _____ years old □ unknown
(if only hypomania first diagnosed hypomanic episode)

10.5. Number of manic episodes _____

10.6. Is there a predominant type of mania that is clearly predominant in this patient's presentation? (Select one) (skip if no history of mania)

□Irritable □elated □mixed

10.7. Has psychosis been present during mania? Yes / No (skip if no history of mania)

10.8. Does the subject have treatment resistant mania? Yes / No
Definition: Not fully responsive to good compliance at therapeutic dose of lithium or mood stabiliser + atypical antipsychotic (skip if no history of mania)

10.9. Number of total mood stabilisers/atypical antipsychotics tried to treat hypomania/mania (circle)

□Unknown □None □1 □2-3 □4-5 □>5

10.10. What is the approximate duration of the total time that the patient was trialled on medication prior to ECT? (select one)

□Unknown □none □ < 3 months □3-6 months □ 6 months - 1 year

□1-2 years □2-3 years □>3 years

10.11. Class of medications trialled for mania ever (circle all drugs and response as applicable)

Typical antipsychotics	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Atypical antipsychotics	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Clozapine	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Benzodiazepine	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Lithium	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor
Anticonvulsant	□Unknown	□No past trial	□Unknown Response	□Good	□Partial	□Poor

11. Bipolar Spectrum Depression History (extended): If the subject has had a diagnosis of bipolar disorder as indicated in 3.4, Please fill in this section (extended)

11.1. Age when subject experienced first unequivocal major depressive episode (may have gone untreated)

_____ □Unknown

11.2. Number of depressive episodes _____ □ Unknown

11.3. Is there a type of depression that is clearly predominant in this patient's presentation? (Select all appropriate)

□Melancholic □ Atypical □ Psychotic □Catatonia □No clear pattern □Unknown

11.4. Did past treatments for depression include? Response? (select all appropriate)

Psychotherapy □Unknown □No past trial □Unknown Response □Good □Partial □Poor

Transcranial Magnetic Stimulation □Unknown □No past trial □Unknown Response □Good □Partial □Poor

Transcranial Direct Current Stimulation □Unknown □No past trial □Unknown Response □Good □Partial □Poor

11.5. Class of medications trialled ever (circle drug and response if appropriate)

SSRIs (fluoxetine, sertraline, paroxetine, (es)citalopram)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

SNRIs (venlafaxine, duloxetine)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

TCAs (amitriptyline, amoxapine, desipramine, imipramine, nortriptyline, protriptyline, trimipramine)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

MAOis (isocarboxazid, phenelzine, selegiline, tranylcypromine)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

Atypical antidepressant agents (bupropion, mirtazapine, nefazodone, trazodone, vilazodone, vortioxetine)
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

Combination use of above antidepressants
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

Ketamine
□Unknown □No past trial □Unknown Response □Good □Partial □Poor

Buspirone

□Unknown □No past trial □Unknown Response □Good □Partial □Poor

Please mark types used in list below

Atypical antipsychotics	□Unknown □No past trial □Unknown Response □Good □Partial □Poor
Benzodiazepine	□Unknown □No past trial □Unknown Response □Good □Partial □Poor
Lithium	□Unknown □No past trial □Unknown Response □Good □Partial □Poor
Anticonvulsant	□Unknown □No past trial □Unknown Response □Good □Partial □Poor
T3 (Liothyronine)	□Unknown □No past trial □Unknown Response □Good □Partial □Poor
Buspirone	□Unknown □No past trial □Unknown Response □Good □Partial □Poor

12. Medical History: extended

12.1. Comorbid medical diagnosis (please type)

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13. Substance Use: extended

13.1. Is there a history of substance use disorder? Yes / No / Unknown

13.2. The subject has the following substance use disorder history (select appropriate)

Alcohol	□current /□past □unk
Stimulants (cocaine/speed/meth)	□current /□past □unk
Opiates	□current /□past □unk
Hallucinogens	□current /□past □unk
Cannabis	□current /□past □unk
Sedative/hypnotic/anxiolytic (Benzodiazepines etc)	□current /□past □unk
Inhalant	□current /□past □unk
Other (list……..)	□current /□past □unk

13.3. Lifetime maximum tobacco smoking history _____

□*Never smoked,* □*<5 cigarettes/ day,* □*5-20 cigarettes/day* □ *>20 cigarettes/day*

14. Family History: (14.1 is extended, 14.2 is conditional on 14.1)

14.1. Is there a family (first degree) history of any psychiatric disorders?
Yes / No/ Unknown (if no or unknown please skip to section 15)

14.2. Select if there are any first-degree family members with the following:

MDD	yes / no / unknown
Bipolar I disorder	yes / no / unknown
Bipolar II disorder	yes / no / unknown
Schizophrenia	yes / no / unknown
Schizoaffective disorder	yes / no / unknown
Anxiety disorder	yes / no / unknown
Dysthymia	yes / no / unknown
Social phobia	yes / no / unknown
Panic disorder	yes / no / unknown
Obsessive-compulsive disorder	yes / no / unknown
Post-traumatic stress disorder	yes / no / unknown
Anorexia nervosa	yes / no / unknown
Bulimia nervosa	yes / no / unknown
Alcohol abuse	yes / no / unknown
Alcohol dependence	yes / no / unknown
Nicotine dependence	yes / no / unknown
Drug induced psychosis	yes / no / unknown
Drug induced mania	yes / no / unknown
Other mental illness	yes / no / unknown

14.3. Please list any other mental illnesses with family history here, separated by commas,
_____

14.4. Suspected (undiagnosed) family history of psychiatric disorders or known family members with Mendelian syndromes Yes / No

15. ECT History: extended. Please skip this section if the answer to 3.1 is No.

15.1. Number of past ECT series?(enter 9999 for unknown) _____

15.2. Age at first ECT (9999 for unknown)_____

15.3. History of Manic Switch Yes / No

15.4. Was ECT ever terminated for manic switch?

15.5. **Add any additional general notes** -

_____

16. Administrative Questions: (16.1-16.4 required)

16.1. Has data entry been finalized for this subject?
(i.e., all the data that can be collected has been collected) Yes / No

16.2. Has blood collection been completed for this subject? Yes / No

16.3. Permission to re-contact for future studies? Yes / No

16.4. Has the informed consent been withdrawn? Yes / No

16.5. Date the informed consent was withdrawn / / Day /Month / Year

16.6. If a reason was given for withdrawing consent, please document here:
_____

16.7. Has the subject become unable to continue participating in the project? Yes / No

16.8. Date it was determined the subject is unable to continue

/ / Day/Month/Year

16.9. Reason the subject is unable to continue _____